

### REMARKS

Claims 1-6 are pending in the application. Claims 1-6 have been amended to better describe certain aspects of the invention. Favorable reconsideration in light of the amendments and the remarks which follow is respectfully requested.

### Amendments

Claim 1 has been amended to exclude compounds described in Kawada et al (HCAPLUS 1998: 239541 and Japan Patent Application Publication No. 10-101615, hereinafter "Kawada"), and Eremin et al (HCAPLUS 1995: 562387, hereinafter "Eremin"), and Rinder et al (HCAPLUS 1981: 401702, hereinafter "Rinder"). Support for the amendment to claim 1 is found in the specification, for example, on page 7, line 7. The amendments to claims 2 and 4 are supported by the specification, for example, on page 11, the first full paragraph to page 12. The amendment to claim 3 is supported by the specification, for example, on page 8, the first paragraph. Claims 5 and 6 have been amended for consistency with the amendments to claims 1 and 3, and support for the amendments to claims 5 and 6 are found in the specification, for example, on page 22, the first paragraph.

### Rejection of Claims 2 and 4-6 Under 35 U.S.C. §112, Second Paragraph

Claims 2 and 4-6 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claims 2 and 4-6 have been amended to better describe certain aspects of the invention. With respect to claims 2 and 4, the claimed immunoassay is described in clear terms so that one skilled in the art can readily understand the metes and bounds of the acts required. With respect to claims 5 and 6, the claimed immunoassay kit is described in clear terms so that one skilled in the art can readily understand the metes and bounds of the subject matter. In particular, with respect to the terms "a primary antibody to dioxins" and a labeled secondary antibody to the primary antibody" in claim 6, the scope of the claim is clear to one skilled in the

pertinent art since these terms are described in the specification, for example, on page 12, the second full paragraph to page 13, the second paragraph. Withdrawal of this rejection is respectfully requested.

**Rejection of Claims 2 and 4 Under 35 U.S.C. §101**

Claims 2 and 4 stand rejected under 35 U.S.C. §101 for an improper definition of patentable subject matter. Claims 2 and 4 have been amended to clearly recite the acts involved in the claimed immunoassay. Such a well described immunoassay is indeed patentable subject matter. Withdrawal of this rejection is respectfully requested.

**Rejection of Claims 1 and 3 Under 35 U.S.C. §102(b) over Kawada, Eremin, and Rinder**

Claims 1 and 3 stand rejected under 35 U.S.C. §102(b) over Kawada, Eremin, and Rinder. Kawada describes a phenoxyacetic acid (II) on page 60 of the HCAPLUS printout. The Applicants respectfully request withdrawal of the rejection for at least the following reasons. Kawada does not disclose each and every feature of claimed invention.

To establish anticipation, 35 U.S.C. §102 requires that each and every element as set forth in the claim is found, either expressly or inherently described, in a single cited art document. Claim 1 has been amended to recite “n is an integer of 5 to 10” to better distinguish Kawada. Claim 3 has been amended to recite “Z is an amino acid or a peptide” to better distinguish Kawada. Kawada fails to disclose a 2,4,5-trichlorophenoxyalkyl carboxylic acid represented by the formula (I), wherein n is an integer of 5 to 10, as required in claim 1. Kawada also fails to disclose a 2,4,5-trichlorophenoxyalkyl amide derivative represented by the formula (II), wherein n is an integer of 1 to 10 and z is an amino acid or peptide, as required in claim 3. Since Kawada fails to disclose each and every feature of claims 1 and 3, Kawada cannot anticipate claims 1 and 3. Hence, the rejections should be withdrawn.

Eremin describes a phenoxyacetic acid and its derivative on pages 72 and 73 of the HCAPLUS printout. The Applicants respectfully request withdrawal of the rejection for at least the following reasons. Eremin does not disclose each and every feature of claimed invention.

Claim 1 has been amended to recite "n is an integer of 5 to 10" to better distinguish Eremin. Claim 3 has been amended to recite "Z is an amino acid or a peptide" to better distinguish Eremin. Eremin fails to disclose a 2,4,5-trichlorophenoxyalkyl carboxylic acid represented by the formula (I), wherein n is an integer of 5 to 10, as required in claim 1. Eremin also fails to disclose a 2,4,5-trichlorophenoxyalkyl amide derivative represented by the formula (II), wherein n is an integer of 1 to 10 and z is an amino acid or peptide, as required in claim 3. Since Eremin fails to disclose each and every feature of claims 1 and 3, Eremin cannot anticipate claims 1 and 3. Hence, the rejections should be withdrawn.

Rinder describes a phenoxyacetic acid on page 86 of the HCAPLUS printout. The Applicants respectfully request withdrawal of the rejection for at least the following reasons. Rinder does not disclose each and every feature of claimed invention.

Claim 1 has been amended to recite "n is an integer of 5 to 10" to better distinguish Rinder. Claim 3 has been amended to recite "Z is an amino acid or a peptide" to better distinguish Rinder. Rinder fails to disclose a 2,4,5-trichlorophenoxyalkyl carboxylic acid represented by the formula (I), wherein n is an integer of 5 to 10, as required in claim 1. Rinder also fails to disclose a 2,4,5-trichlorophenoxyalkyl amide derivative represented by the formula (II), wherein n is an integer of 1 to 10 and z is an amino acid or peptide, as required in claim 3. Since Rinder fails to disclose each and every feature of claims 1 and 3, Rinder cannot anticipate claims 1 and 3. Hence, the rejections should be withdrawn.

**Rejection of Claims 5 and 6 Under 35 U.S.C. §103(a) over Kawada, Eremin, and Rinder**

Claims 5 and 6 stand rejected under 35 U.S.C. §103(a) over Kawada, Eremin, and Rinder. The Applicants respectfully request withdrawal of the rejection for at least the following reasons. The cited art does not teach or suggest all the features of the claimed invention.

To reject claims in an application under §103, an examiner must establish a *prima facie* case of obviousness. A *prima facie* case of obviousness is established by a showing of three basic criteria. First, there must be some suggestion or motivation, either in the cited art or in the knowledge generally available to one of ordinary skill in the art, to modify or combine cited art teachings. Second, there must be a reasonable expectation of success. Finally, the cited art must teach or suggest all the claim features. See MPEP §706.02(j).

In addition, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the cited art and not based on applicant's disclosure. See *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Kawada, Eremin, and Rinder fail to teach or suggest a 2,4,5-trichlorophenoxyalkyl carboxylic acid represented by the formula (I), wherein n is an integer of 5 to 10, as required in claim 1. Kawada, Eremin, and Rinder also fail to teach or suggest a 2,4,5-trichlorophenoxyalkyl amide derivative represented by the formula (II), wherein n is an integer of 1 to 10 and z is an amino acid or peptide, as required in claim 3.

In the field of immunoassays, the structure of a competitive antigen used for the detection of the objective material is important. This is because the sensitivity of detection is directly related to the ability/inability to bind with another compound, and binding is determined by structure. In the claimed invention, dioxins can be specifically detected by using the claimed compounds of formulae (I) and (II) as competitive antigens. These competitive antigens have a minimum cross-reaction with other compounds, such as chlorobenzenes and chlorophenols. For example, Example 4 of

the specification shows that a competitive antigen of 6-(2,4,5-trichlorophenoxy) hexanoic acid amide derivative (IIa) specifically cross-reacts with dioxins, while the competitive antigen does not show cross-reactions with polycyclic aromatic hydrocarbons and chlorinated compounds such as PCBs (Tables 2 and 3 of the specification).

The compounds of Kawada, Eremin, and Rinder are structurally different from those of claims 5 and 6. The structural differences lead to differences in binding/reacting to other substances. Since the cited art does not teach or suggest the structures of claimed compounds of formulae of (I) and (II), one skilled in the art would not have been motivated by Kawada, Eremin, and/or Rinder to provide compounds that are competitive antigens for dioxins, but not for other compounds such as chlorobenzenes and chlorophenols. In view of the foregoing, the rejection should be withdrawn.

**Rejection of Claims 1, 3, 5 and 6 over Fujirebio JP 2002-128731 and JP 2002-131316**

Claims 1, 3, 5 and 6 stand rejected under 35 U.S.C. §102(a) or, in the alternative, under §103(a) over each Fujirebio JP 2002-128731 and JP 2002-131316. JP 2002-128731 relates to an assay to determine the amount of PCBs by an immunoassay method using compound I at page 2 of JP 2002-128731 as a competitive antigen. JP 2002-131316 relates to an assay to determine the amount of organic chlorine compounds such as PCBs and dioxins by an immunoassay method using compound I at page 2 of JP 2002-131316 as a competitive antigen. The Applicants respectfully request withdrawal of the rejections for at least the following reasons. The cited art does not disclose, teach, or suggest all the features of the claimed invention.

The claimed invention addresses an assay to specifically detect dioxins by using the claimed compounds of formulae (I) and (II) as a competitive antigen. As shown in Tables 2 and 3 of the specification, the claimed invention can detect dioxins (Table 2 of

the specification), but does NOT cross-react with chlorinated compounds such as PCBs, chlorobenzenes, and chlorophenols (Table 3 of the specification). In the claimed compounds, a chlorine atom is in the position ortho to the alkylcarboxylic acid (formula (I)) or alkyl amide group (formula (II)). JP 2002-128731 and JP 2002-131316 are different from the claims because JP 2002-128731 and JP 2002-131316 do not disclose, teach, or suggest any phenylacetic acid derivatives that have a chlorine atom in the ortho position (see paragraphs, for example, 0025 and 0027 of JP 2002-128731 and paragraphs, for example, 0023 and 0030 of JP 2002-131316). That is, the cited art, alone or in combination, fail to disclose, teach or suggest all the claim features.

In this connection, structural differences between the detected compounds may require a specific structure of a competitive antigen for selective detection. Although both PCBs and dioxins have two benzene rings, the physical structure is quite different. For example, one of the structural differences is that PCBs have a biphenyl structure that allows rotation of two benzene rings about each other providing many three dimensional conformations, whereas dioxins have two oxygen atoms that fix the two benzene rings, thereby giving dioxins a relatively stable planar structure. These different structural conformations have an impact on the ability to bind/react to certain compounds. Consequently, structures of the objective compounds for detection are quite different from each other.

It would NOT have been obvious for one skilled in the art to modify the cited art to achieve the claimed invention since the compounds of JP 2002-128731 and JP 2002-131316 do NOT specifically bind to dioxins. The structure of dioxins is different from that of PCBs and as a result, different compounds are needed for binding. JP 2002-128731 discloses that the phenylacetic acid compounds described therein can be used for PCB assays. JP 2002-131316 discloses that the phenylacetic acid compounds described therein can be used for assays of PCBs and dioxins. By using such compounds of the cited art, however, dioxins cannot be specifically detected. For example, Table 3 of JP 2002-131316 shows that the compounds therein do not cross-

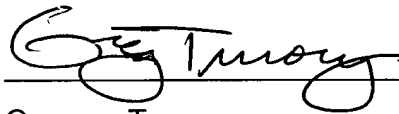
react with dioxins. Contrary to the teachings of the cited documents, the claimed invention can specifically detect dioxins by using the specific compounds of formulae of (I) and (II). One skilled in the art would not confuse these objectives. Consequently, it would not have been obvious for one skilled in the art to achieve the claimed invention that provides dioxin-selective detection, based on the teachings of the cited art that involves PCBs detections. In view of the foregoing, the rejection should be withdrawn.

Should the Examiner believe that a telephone interview would be helpful to expedite favorable prosecution, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

In the event any fees are due in connection with the filing of this document, the Commissioner is authorized to charge those fees to our Deposit Account No. 50-1063.

Respectfully submitted,

**AMIN & TUROCY, LLP**

A handwritten signature in black ink, appearing to read "Greg Turocy", is written over a horizontal line.

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